



Smallpox Vaccine and Myo/pericarditis Case-Control Study

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Smallpox Vaccine and Myo/pericarditis Case-Control Study Background

- ◆ DoD Smallpox Vaccination Program
 - Introduced December 2002
 - Myopericarditis cases begin February 2003
- ◆ Case-control study
 - Conceived during DoD/CDC/FDA teleconference
 - Funded by MILVAX in August 2003



Smallpox Vaccine and Myo/pericarditis Case-Control Study Design



- Limit to male, primary vaccinees, aged 20-45 years, serving on active duty for six or more months during December 1, 2002 to August 31, 2003
- Ascertain study subjects, demographics, addresses from DMDC
- Enroll 4 controls per case
- Postal enrollment by NHRC
- Computer assisted telephone interviews (CATI) by contract

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- Ascertain from M2 (SIDR, SADR, HCSR), others?
- ICD-9-CM:
 - 420.9x, Other & unspecified acute pericarditis
 - 422.90, Acute myocarditis, unspecified
 - 422.91, Idiopathic myocarditis
 - 422.99, Other acute myocarditis
 - 429.0, Myocarditis unspecified

Smallpox Vaccine and Myo/pericarditis Case-Control Study Analysis



- Logistic regression analysis with adjustment for:
 - Age at vaccination
 - Service and occupation
 - Race/ethnicity
 - Education
 - Concomitant vaccinations
 - Exercise, smoking, alcohol usage, prescription and over the counter medications, dietary supplements, deployments
 - Past illnesses, including past diagnoses of myopericarditis
 - Illnesses at the time of, or within 30 days of, smallpox vaccination

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- NHRC IRB approval November 2003
- Case ascertainment nearing completion
- Procure DMDC Report Control Symbol (RCS) in progress
- Solicitation for CATI at contracting
- Anticipate:
 - Enrollment in June-July 2004
 - Interview July-August 2004
 - Results September-October 2004



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